I. 7.2.2 Institutional Review Board Responsibilities

Chapter 7 - Research and Sponsored Programs	Original Effective Date: May 2008
Section: 7.2 Human Research Protection Program	Date Last Reviewed: March 2026
Responsible Entity: Senior Executive Vice President for Research and Innovation	Date Last Revised: March 2026

II. Purpose

The University of Texas Health Science Center at San Antonio (UT Health San Antonio, or the Institution) has assured the Department of Health and Human Services (DHHS) of compliance with DHHS regulations (45 CFR § 46.103) for the protection of human subjects, through an Office of Human Research Protection (OHRP) approved Federalwide Assurance (FWA00005928).

III. Scope

When the Institution becomes engaged in research to which the FWA applies, the Institution and institutional review boards (IRBs) upon which it relies for review of such research will comply with the Common Rule. The FWA covers all UT Health San Antonio-controlled affiliates, including but not limited to its schools, clinics, hospitals, and research activities.

IV. Policy

The Institution established the IRBs in accordance with the Institutional Handbook of Operating Policies (IHOP) 1.6.6 Institutional Review Board. The Institution grants its IRBs the authority to:

1. Approve, require modifications to secure approval, or disapprove all research activities overseen and conducted by the organization and/or its employees or agents.
2. To suspend or terminate approval of research not being conducted in accordance with the IRB's requirements or that has been associated with unexpected harm or increased risk to participants.
3. To observe, or have a third party observe, the consent process.
4. To observe, or have a third party observe, the conduct of the research.
5. To investigate allegations of non-compliance with institutional policies or research regulations, as well as reports of unanticipated problems. In cases where corrective

action is needed, the IRB may take appropriate actions including (but not limited to) requiring modifications, determining data collected cannot be used for publication, suspending or terminating approval, requiring additional education, and recommending further action(s) to the Institution's administration such as disqualifying investigators from conducting research involving human subjects.

6. The IRB presents these determinations to the Institutional Official (IO), in whom ultimate approval authority is vested; for affiliated institutions relying on the IRB, ultimate approval authority is described in the Memorandum of Understanding (MOU) or other agreement between the institutions. Determination shall be presented in the form of IRB minutes presented for IO signature. The IO may accept, add additional restrictions to, or reject some or all of the determinations of the IRB, with the exception that the IO cannot approve research involving human subjects that has not been approved by the IRB (e.g., tabled/deferred or disapproved by the IRB). Likewise, other officials or committees of the organization may not approve the research if it has not been approved by the IRB.

The authority granted to the IRBs is in accordance with 45 CFR Part 46, 21 CFR Parts 50 and 56, and 38 CFR Part 16.

Where research includes information covered under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the IRBs have authority to act as Privacy Boards to review, approve, require modifications, or disapprove requests for alteration, waiver, or partial waiver of authorization required for use or disclosure of protected health information as described in 45 CFR Part 164.508.

A. Independence of the IRB

The Institution grants the IRBs the authority to act independently to bind all activities falling under the authority listed above. All Institutional personnel who become aware of attempts to inappropriately influence the IRB are to report such incidents to the IRB Director, who notifies the IO. The IO, in consultation with the IRB Director and other appropriate institutional leadership, will evaluate the allegation. If the allegation is validated, they will determine the appropriate response, and any action required will be taken by a supervisor at the department level or higher. Responses may range from an oral or written reprimand up to and including suspension of the individual from some or all current and future research activities under the review of the IRBs. The IO may also refer the issue for additional institutional action.

B. IRB Policy Development

The IRB Director develops and implements written IRB policies and procedures under applicable regulations for the protection of human subjects, in consultation with the Executive Leadership of the Office of the Senior Executive Vice President for Research and Innovation (VPR).

C. Knowledge, Skills, and Abilities of Members

1. The IRB Chairs, members (primary and alternate), and IRB Director and staff must be familiar with the ethical principles guiding human research; the requirements of federal regulations, applicable state law, the institution's FWA; and institutional policies and procedures established for the protection of human subjects. The IRBs as a whole must also have effective knowledge of subject populations and other factors that can potentially contribute to a determination of risks and benefits to subjects and that can impact participants' informed consent.
2. New members to the IRB shall receive orientation from the IRB Chairs, Director, or designee. Members complete required training and receive continuing education as outlined in applicable IRB education policies. Continuing education is provided during convened IRB meetings, may include topics such as current ethical challenges or applying federal regulations, and is documented in meeting minutes.

D. Removal of IRB Members

Members may be disqualified from the IRB for scientific misconduct, unethical behavior, conflict of interest, non-compliance with the rules governing the IRB, or failure to actively participate. Such concerns are forwarded to the IO for review and action, as appropriate.

E. Meetings

IRBs meet regularly to review new studies, requests for continuation or modification of approved research, and reports of non-compliance or unanticipated problems for non-exempt human research. The IRB Director establishes the meeting schedule. The IO may direct, and the IRB Director or Chair may convene, additional meetings any time.

F. Affiliated Institutional Responsibilities

The IRBs may provide review and continuing oversight of some or all research conducted at affiliated institutions through a valid signed IRB Authorization Agreement. Affiliates relying on the Institution's IRBs remain responsible for ensuring compliance with the IRB's determinations, applicable institutional policies, and the terms of its OHRP-approved FWA.

Written procedures for reporting findings and actions to appropriate officials are documented in valid signed MOUs with institutions relying on the IRBs for all or most of their research.

V. Definitions

When used in this document, the following words have the meaning set forth below unless a different meaning is required by context.

Institutional Official (IO) – Institutional official who is legally authorized to act on behalf of the institution and is responsible for ensuring compliance with federal, state, and local laws and regulations for human subjects research. The IO for UT Health San Antonio is the Senior Executive Vice President for Research and Innovation.

VI. Related References

IHOP 1.6.6 Institutional Review Board

IHOP 7.2.1 Human Research Protection Program Responsibilities

VII. Review and Approval History

The approving authority of this policy is the University Executive Committee.

Effective Date	Action Taken	Approved By	Approved Date
05/2008	Policy Origination		
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03/2026	Policy Revision	Executive Committee	03/20/2026